Technical Field of the Invention

The present invention relates to the general art of surgery, and to the particular field of introducing material to a patient for therapeutic or diagnostic purposes, most specifically, the invention relates to NO therapy.

Cross Reference to Related Applications

The present application is a continuation-in-part of application Serial Number 10/351,755, filed on 01/27/2003 which is a continuation-in-part of application of Serial Number 09/688,229 filed on 10/16/2000, both of which are owned by the assignee of the present application. The present application incorporates herein the disclosures of the 09/688,229 and the 10/351,755 patent applications by reference.

Background of the Invention

As discussed in the referenced and incorporated disclosure, the use of therapeutic gases to treat a human or animal patient has been known in the art for many years. A number of different gases may be added to a respiratory gas that is inhaled by a patient. It is noted that this application merely refers to a "patient" because it is intended to encompass within its scope the following situations: a spontaneously breathing, non-ventilated patient, as well as a spontaneously breathing, mechanically-ventilated patient, as well as a non-spontaneously

breathing, mechanically-ventilated patient. Accordingly, the term "patient" is intended to cover all of these situations and/or combinations thereof. These gases may be used to achieve some therapeutic effect, service a diagnostic function or have some other desirable purpose. Such gases will be referred to herein as therapeutic gases. One skilled in the delivery of therapeutic gas will understand that the disclosure can be used to teach either human or animal patients. Accordingly, no limitation to human is intended by references to patient in this disclosure.

One therapeutic gas is nitric oxide (NO), which is administered by inhalation in low concentrations to treat primary or secondary pulmonary hypertension or other diseases. In many cases, nitric oxide or other therapeutic gases come from a high concentration source such as a high concentration compressed gas cylinder. The gas source may be pure or may contain some concentration of therapeutic gas in a carrier gas. There may also be cases where more than one therapeutic gas is used, with or without a carrier gas or gases. It is often necessary to dilute therapeutic gas to a lower concentration and mix it with air and/or oxygen prior to delivery to the patient. This dilution may be necessary to achieve a desired dosage concentration and/or to avoid or reduce adverse bioeffects that may occur if high concentration gas is delivered to the patient. If the

therapeutic/carrier gas is not sufficiently oxygenated, it is necessary to mix it with air prior to delivery to the patient. In some cases, it is necessary to add supplemental oxygen to the mixture to avoid a hypoxic respiratory mixture or to enrich the oxygen content of the respiratory gas above twenty-one percent. In the latter case, the oxygen will also be considered as a therapeutic gas.

NO is one of a number of therapeutic gases that are administered to a patient and require dilution from a high concentration form to a lower, safer concentration before administration to a patient. NO will be the primary focus of this disclosure; however, one skilled in the surgical arts will understand that the disclosure can be used to teach other gases as well. Accordingly, no limitation to NO is intended by the references to NO in this description.

The art contains several devices and systems to deliver therapeutic gas to a patient.

The referenced and incorporated disclosure discusses several systems for administering therapeutic gas to a patient.

Many systems that are used to administer therapeutic gas to a patient include primary gas sources in the form of pressurized cylinders. Some of these systems include a flow direction check valve downstream of the inlet to seal the downstream portions of

the system when the supply pressure is removed. However, a check valve isolation system may have drawbacks if used in certain circumstances.

When a pressurized gas source is exchanged, there exists the possibility that air will be trapped within the inlet volume of the system plumbing that is exposed to air during the source exchange. Specifically, in a check valve system, this volume includes the volume upstream of the sealing mechanism of the check valve. It is desirable to keep that exposed volume of plumbing as small as possible so the resulting trapped air volume is reduced. Any trapped air will normally degrade the quality of the high purity gases contained within the remainder of the system when intervening valves are opened. This degradation is proportional to the volume of trapped air.

As discussed in the incorporated material, it is desirable to maintain this dead volume to a minimum. Note that the concept of dead volume should also be read to include dead surface area within the scope of this discussion. The trapped air volume will also be referred to as the dead volume in this disclosure. Surface area plays an important role in gas plumbing quality since contaminants often preferentially adhere to surfaces and can be extremely difficult to remove.

Furthermore, it is advantageous to provide a system sealing

action as close to the supply inlet as possible to further minimize the dead space volume upstream of the sealing surfaces.

Typically, a flow direction check valve is not able to achieve all of these goals.

It is noted that it is possible to flush or purge the system to remove contaminated gas from dead space regions and other parts of the gas circuit. However, for purging to be effective, the dead space and other parts of the gas circuit must be substantially swept out and internal surfaces scrubbed by periods of high gas flow. If there are poorly swept regions within the gas circuit, purging will have to be extended to allow for diffusion and other gas exchange mechanisms to remove or dilute the contamination. Therefore, there is a need for a means for ensuring proper purging of a system used to administer therapeutic gas to a patient. However, if purging requires the use of supply gas, it will be advantageous to use the minimum amount of gas possible. On the other hand, however, the purge must be as complete as possible.

Therefore, there is a need for a method of purging a system such as disclosed in the incorporated material in a manner that is effective yet which makes the most efficient use of purging gas.

Furthermore, as discussed in the incorporated material,

purging requirements are strongly dependent on the relative size and geometry of the contaminated volumes and surfaces. Purging is often complicated in many situations due to possible toxic effects of the therapeutic gases on bystanders and the high cost of medical grade gases.

The incorporated disclosure also notes that there is a further need for a valve that will make purging most efficient and effective.

Furthermore, the referenced and incorporated disclosure notes that an autonomous gas delivery system should be able to detect the supply pressure so when a pressurized cylinder has been attached and the supply valve opened, a control system is signaled.

As discussed in the incorporated material, when a gas source is changed or is otherwise disconnected and then reconnected, there is a need to ensure that the system has the proper amount and purity of therapeutic gas when the system is used to administer that gas to a patient. Thus, proper purging is important in such a system. However, this purging must be achieved in an efficient manner to avoid wasting therapeutic gas.

Therefore, there is a need for a method for efficiently and effectively purging a system and elements such as disclosed in the incorporated material which delivers NO to a patient and

purging the system when the therapeutic gas source is changed or is otherwise disconnected and then reconnected.

The referenced and incorporated disclosure further notes that in order to maintain low inlet dead space, a supply pressure sensor must be located on the downstream side of an inlet sealing mechanism. In the prior art, a simple back flow prevention check valve has provided this function. A check valve will seal when there is a lower supply pressure on the upstream side of the check valve than in the downstream plumbing (thus checking the backward flow of gas). If the check valve seals, the pressure sensor, which is located further downstream in the system than the check valve, will continue to show the last supply pressure when the check valve closes. The pressure sensor may not indicate the actual supply pressure, which typically drops to atmospheric pressure when the supply is disconnected. If, subsequent to this, a supply is attached that is at a lower pressure than the checked pressure, the system will not be able to detect the connection until the pressure downstream of the check valve has been bled off or not at all.

Accordingly, as discussed in the referenced and incorporated disclosure, there is a need for a means for sealing a system such as disclosed herein which will be able to fully detect pressure and control the flow of the system during changing of gas

sources.

Purging should be as efficient as possible. Therefore, a purging method should be versatile.

Therefore, there is a need for a repeatable method by which purging can be performed so that the system may be cleared of excessive contamination in a reliable fashion and that the purge process be effective under manual, semiautomatic or fully automatic control.

The referenced and incorporated disclosure observes that in general, it is desirable to close off the inlet of a system such as disclosed herein when a supply is detached and to maintain the inside of the high purity system at a slight positive pressure with respect to atmospheric pressure.

The advantages of this isolated input but slight remaining positive pressure situation include: the chance of contamination is reduced; minor leaks that may be present will tend to leak in an outward fashion; the limited maximum internal to inlet side pressure allows the downstream pressure sensor to detect a disconnection of a supply with any significant pressure; and allows the system to detect the connection of another supply with a pressure significantly above atmospheric.

As discussed in the referenced and incorporated disclosure, there is a need for a means for connecting the system of the

present invention to a source of gas that will reduce the possibility of contamination of the system. Therefore, there is a need for a mechanism that can minimize dead space volume.

The referenced and incorporated disclosure discusses an equalizing valve that simultaneously satisfies a number of objectives and overcomes many problems associated with prior therapeutic gas delivery systems.

Still further, there are situations in which the main supply source for a system must be removed from the system. For example, the main source must often be removed to be replaced with an alternate source. Replacement may be required if: the primary source is depleted; if a portable gas source is being replaced by a stationary source (or vise versa); or if the gas source is being exchanged for an alternate therapeutic gas composition. Other situations that may require the removal of the gas source include but are not limited to preparation for temporary storage or shipment, periodic maintenance and transport between use locations.

As discussed in the referenced and incorporated disclosure, contamination of the therapeutic gases, such as mixing therein atmospheric gases, is undesirable.

In many therapeutic gas delivery situations, gas delivery to the patient must be temporarily disrupted in order to change

supply source, or the like. Such disruption is undesirable. In order to obviate such disruption, some gas delivery systems include either a second large source or an external back-up source of therapeutic gas. Either of these solutions can be costly and cumbersome.

Still further, if, for some reason, the primary gas source ceases supplying gas to the system and an operator does not immediately replace the gas source, delivery of gas to the patient may be interrupted, or even contaminated. Neither of these situations is desirable.

Therefore, there is a need for a therapeutic gas delivery system in which continuous gas delivery to a patient is ensured, even if the main gas source ceases delivering gas for a short period of time.

Objects of the Invention

It is a main object of the present invention to provide a method for efficiently and effectively purging a system and elements such as disclosed in the incorporated material which deliver NO to a spontaneously breathing, and/or a non-spontaneously breathing and or a mechanically ventilated patient or a non-ventilated patient.

It is another object of the present invention to provide a method for efficiently and effectively purging a system and

elements such as disclosed in the incorporated material which delivers NO to a patient that is easily and effectively performed.

It is another object of the present invention to provide a method for efficiently and effectively purging a system and elements such as disclosed in the incorporated material which delivers NO to a patient and which has a means for effectively and efficiently equalizing pressure between a source of pressurized gas and the system, but keeping the system pressurized slightly above atmospheric pressure if the gas source is removed.

It is another object of the present invention to provide a method for efficiently and effectively purging a system and elements such as disclosed in the incorporated material which delivers NO to a patient that includes a means for ensuring proper purging of a system used to administer therapeutic gas to the patient.

It is another object of the present invention to provide a system and elements for delivering NO to a patient that includes a valve that will make purging most efficient and effective while overcoming the problems associated with the prior art.

It is another object of the present invention to provide a repeatable method by which purging can be performed so that the

system may be cleared of excessive contamination in a reliable fashion and that the purge process be effective under manual, semiautomatic or fully automatic control.

It is another object of the present invention that the purge process use a minimum of supply gas to minimize operator, patient or bystander hazards and to conserve source gas for therapy.

It is another object of the present invention to provide a method for efficiently and effectively purging a system and elements such as disclosed in the incorporated material which delivers NO to a patient and purging the system when the therapeutic gas source is changed or is otherwise disconnected and then reconnected.

It is another object of the present invention to provide a method for efficiently and effectively purging a system and elements such as disclosed in the incorporated material which delivers NO to a patient and topping up the reservoir with clean gas after reconnecting the therapeutic gas source, but prior to the completion of the purge required when the therapeutic gas source is reconnected.

It is another object of the present invention to provide a method for efficiently and effectively purging a system and elements such as disclosed in the incorporated material which delivers NO to a patient and automatically detecting when a

therapeutic gas source is reconnected to the system.

Summary of the Invention

These, and other, objects are achieved by a system that administers therapeutic gas to a patient which incorporates all of the teaching of the referenced and incorporated disclosure and which includes one or more equalizing valves fluidically connecting a source of therapeutic gas to the system. A reservoir is included in the system to ensure continuous supply of therapeutic gas to the patient even if the main source of therapeutic gas is temporarily interrupted.

The equalizing valve discussed in the incorporated material satisfies the objects stated in the incorporated material. The valve is positioned directly at the inlet of the devices gas system by being incorporated into the supply connection fitting. The equalizing valves sealing surfaces within the fitting is located close to the tip of the connection fitting. The remaining upstream volume of the connection fitting is reduced by substantially filling that volume with a pin, leaving only a thin annulus for gas to pass into the system. This geometry helps preserve the downstream gas purity and will significantly reduce the required amount of gas for each purge cycle. The equalizing valve also permits proper supply pressure detection and subsequent purging of the system when necessary as discussed

previously.

As discussed in the incorporated disclosure, the equalizing valve operates to pass flow in either direction as long as a minimum value of differential pressure exists across it. When this minimum differential pressure is not met, the equalizing valve seals and prevents flow in either direction. This provides for a dead band in the flow action through the valve.

The equalizing valve also permits easy use of several sources of therapeutic gas. Thus, for example, a portable source can be easily changed over to a bedside source, or several small sources can be used in place of a single large source. Changing of source gas is made easy because the equalization valve keeps the system clean.

The valve maintains a sufficient positive internal pressure to ensure that air does not migrate into the high purity gas regions while a source gas is disconnected. Furthermore, gas is not allowed to enter the reservoir and the source is not connected to the patient until a sufficiently high supply pressure is attached to the system, the pressure is detected and a purge cycle is completed. As an added safety feature, the valve of the present invention automatically throttles itself in the event of a massive downstream leak.

The underlying method by which the above described system

can be effectively purged is based upon repeated pressurization and depressurization of the volume being purged. This action combines flow rinsing of the actively swept regions and surfaces with the contamination dilution affected in both the actively swept regions and unswept regions as they are repeatedly pressurized and depressurized with progressively less contaminated gas. In the system that is being described, this basic operation is performed many times in a controlled sequence by repeatedly pressurizing and depressurizing the gas within the affected volumes while periodically venting portions of the gas, to enhance the rinsing and dilution effects. The gas is shifted forward and backward in the affected volumes in some cases.

It should be understood that where the terms measure, monitor, open, close and the like are used, that in the context of manual, semi-automated or fully automatic systems, these functions could be optionally or alternatively controlled either through the manual intervention of the operator or through the use of computerized control, without the underlying method being affected.

In the preferred embodiment, the purge procedures would be fully automatic with the exception of having to prompt the user to actuate the cylinder valve. This deviation from fully automatic operation is provided as a safety feature so that the

system cannot activate a cylinder without the operator's direct intervention. Alternatively, the system may be automated to the point of prompting the operator to perform the actions in the proper order through otherwise manual means.

Brief Description of the Drawing Figures

Figure 1 is an overall schematic of one form of the system embodying the invention disclosed in the referenced and incorporated material.

Figure 2 is a pressure equalization valve in conjunction with a source of gas as used in conjunction with a system embodying the invention disclosed in the incorporated material and corresponds to Figure 15 of the referenced and incorporated disclosure of Serial Number 09/688,229.

Figure 3 shows the pressure equalization valve of Figure 2 in a first condition and corresponds to Figure 16 of the referenced and incorporated disclosure of Serial Number 09/688,229.

Figure 4 shows the pressure equalization valve of Figure 2 in another condition and corresponds to Figure 17 of the referenced and incorporated disclosure of Serial Number 09/688,229. Note that the difference between Figures 3 and 4 is in the relative positioning of the plunger and seal face. The plunger position is a function of the direction and magnitude of the instantaneous differential pressure on the valve plunger.

Figure 4a indicates the relative flow characteristics of the equalizing valve under various differential pressure and flow conditions. Note the deadband region around zero differential pressure indicating that the flow becomes zero before the magnitude of the differential pressure reaches zero.

Figure 5 shows an alternative form of the equalizing valve embodying the invention disclosed in the referenced and incorporated material with an O-ring seated on a moving plunger.

Figure 6 shows an alternative form of the equalizing valve included in the invention disclosed in the referenced and incorporated material with an O-ring seated on the stationary valve body.

Figure 7 shows a reservoir used in the system embodying the invention disclosed in the incorporated material.

Figure 8 is a detailed schematic of a system embodying the teaching of the invention in the incorporated material in which circuits for alarms, monitors and the like are indicated.

Figure 9 illustrates an alternative form of the system shown in Figure 1 with a reservoir located upstream of a first pressure sensor.

Figure 10 shows an alternative form of the reservoir unit included in the system embodying the invention disclosed in the incorporated material.

Figure 11 shows another alternative form of the reservoir

unit included in the system embodying the invention disclosed in the incorporated material.

Detailed Description of the Invention

Other objects, features and advantages of the invention will become apparent from a consideration of the following detailed description and the accompanying drawings.

BROAD SYSTEM

Referring to Figure 1, the invention disclosed in the incorporated material is broadly embodied in a system 10 for use in administrating therapeutic gas to a patient. System 10 comprises a first equalization valve 12 that is fluidically connected to a source 14 of therapeutic gas. A first fluid conduit 16 has an inlet end 18 fluidically connected to the first equalization valve to receive fluid from source 14. For purposes of this disclosure, the terms upstream and downstream as well as source side and system side will be with reference to a flow direction from source 14 toward a patient with the flow direction being indicated in Figure 1 by arrow F. Other terms, such as inlet and outlet will also be with reference to those flow directions.

As will be discussed below, first equalization valve 12 includes elements to define an equalization pressure between the first fluid conduit and the source of therapeutic gas. The elements are movable to immediately change the position of the

equalization valve plunger when there is a change in fluid pressure in either the source of therapeutic gas or in the first fluid conduit to equalize the pressures on either side of the valve. This differs from the action of a check valve which will delay such equalization when the source pressure drops.

System 10 further includes a second equalization valve 20 which is similiar to the first equalization valve and operates the same way. Second equalization valve 20 is fluidically connected to outlet end 22 of fluid conduit 16 to receive fluid therefrom. The fluid conduit can include several fluid connections, including several equalization valves and a selector valve, so a plurality of gas sources can be used in place of the single gas source shown in Figure 1. Such plural connections are not shown for the sake of convenience as those skilled in the art will understand what is required to achieve such plural connections based on the teaching of this disclosure.

System 10 further includes a first fluid manifold 90 which has an inlet end 94 fluidically connected to second equalization valve 20. Second equalization valve 20 includes elements to define an equalization pressure between the first fluid conduit and the first fluid manifold. The elements of equalization valve 20 are movable to immediately change the valve plunger position when there is a change in fluid pressure in either the first fluid conduit or in the first fluid manifold to equalize the

pressure on either side of the valve.

A first pressure sensor 36 is fluidically connected to first fluid manifold 90. First pressure sensor 36 includes a signal generator 38 which generates a signal corresponding to fluid pressure in the first fluid manifold adjacent to inlet end 94 of the first fluid manifold. Signal generator 38, like the signal generators and signal receivers discussed in this disclosure can be an off-the-shelf item and the details thereof will not be discussed as those skilled in the art will be able to understand the type and operation of such elements based on the teaching of this disclosure.

A first pressure regulator 40 is fluidically connected to the first fluid manifold. The outlet of the pressure regulator 40 is connected to a second fluid manifold 91. It is noted that elements 16, 90 and 91 can also be referred to as a first set of fluidic plumbing as well as other elements including, but not limited to, regulator 40. A pressure relief valve 50 is fluidically connected to the second fluid manifold downstream of the pressure regulator.

A first solenoid controlled valve 54 is fluidically connected to the second fluid manifold and includes a signal receiver 56 which controls operation of the first solenoid controlled valve in accordance with signals received. Valve 54 is controlled by a central processor which opens and closes valve 54

to purge at appropriate times. The central processor receives signals from sensor 36 and includes timing circuits.

A muffler 60 is fluidically connected to said first solenoid controlled valve and vents to atmosphere.

A second solenoid controlled valve 64 is fluidically connected to the second fluid manifold and includes a signal receiver 66 which controls operation of the second solenoid controlled valve in accordance with signals received from, for example, pressure sensor 36. The outlet of valve 64 is connected to the third fluid manifold 92.

The third fluid manifold is fluidically connected to a fluid reservoir unit 72. Inlet end 74 of a fourth fluid manifold 93 is fluidically connected to the fluid outlet of hollow housing 78 of the reservoir. Fluid flowing from the third fluid manifold thus moves through the fluid reservoir and then flows to the fourth fluid manifold. Flow entering the reservoir thus flows in a counterflow direction to fluid exiting the reservoir as will be understood from the following discussion. This counterflow arrangement acts against stagnation of fluid in the reservoir.

A second pressure sensor 80 includes a signal generator 82 and is fluidically connected to the fourth fluid manifold. Alternatively, pressure sensor 80 could be connected to the third fluid manifold rather than to the fourth fluid manifold. Signal generator 82 generates a signal corresponding to fluid pressure

of fluid in the fourth fluid manifold.

A second pressure regulator 84 is fluidically connected to the fourth fluid manifold. The outlet of the second pressure regulator 84 is connected to a fifth fluid manifold 95.

An alarm unit A is electrically connected to the signal generators discussed above so an operator will be alerted to the state of the system. The electrical connection can be via electrical connectors or over the air.

Operation of the broad system

Operation of the broad system 10 is generally as follows. During normal operation with a source of therapeutic gas connected to the system, gas flows through the equalizing valves to the first fluid manifold where the pressure is monitored. The therapeutic gas then flows through the second and third fluid manifolds into fluid reservoir 72 and fluid from the reservoir flows to the patient via the fourth and fifth fluid manifolds.

However, if the pressure in source 14 drops (because, for example, the source is depleted or has been removed for replacement), such pressure drop is immediately passed to the first fluid manifold because of the operation of the equalizing valves and is sensed by pressure sensor 36. It is noted that as with valve 54, valve 64 is controlled by a central processor. This pressure sensor then generates a signal which causes solenoid controlled valve 64 to close thereby sealing off the

system downstream of valve 64 from contamination which may move thereinto when the system is repressurized when a new gas source is connected. Therapeutic gas continues to be supplied to the patient from the reservoir.

When pressure in the first manifold increases as sensed by pressure sensor 36 because, for example, a new source of therapeutic gas is connected to the system, the system upstream of valve 54 will be purged before it is connected to the patient to be sure that any impurities that may have been introduced into the system upstream of valve 54 when the system was not connected to a source of gas are removed before this portion of the system is opened to the patient. The purge embodying the present invention will be fully described below.

An alternative form of the system is shown in Figure 9 as system 10'. System 10' is similar to the just-discussed system 10 except that reservoir 72' is located upstream of first pressure regulator 40 in system 10'. Second solenoid controlled valve 64 and opening valve 54 are also located upstream of first pressure regulator 40. System 10' operates in a manner similar to system 10 and thus will not be further discussed.

EQUALIZING VALVE

The equalizing valve is discussed in the referenced and incorporated disclosure and this discussion is included herein for the sake of completeness. It is also noted that if more than

one equalizing valve is included in the system, all such equalizing valves are similar in function and operation. Thus, only one equalizing valve will be described, it being understood that the description will be applicable to any and all equalizing valves used in the system.

Referring to Figures 2, 3 and 4 (which correspond to Figures 15, 16 and 17 of the referenced and incorporated disclosure), a pressure equalization valve 200 is shown that equalizes pressure on the two sides of the valve until the pressure on the high side of the valve is less than or equal to the pressure on the low side plus the difference that will be referred to as the equalization pressure.

The valve may have a symmetrical pressure flow characteristic where the equalization pressure is the same regardless of which side of the valve is high, or it may have an asymmetrical characteristic with a different equalization pressure depending on which side of the valve has the higher pressure. That is: (high side pressure - low side pressure) ≤ equalization pressure 1, cylinder pressure is higher than system pressure; (high side pressure - low side pressure) ≤ equalization pressure 2, system pressure is higher than cylinder pressure; equalization pressure 1 = equalization pressure 2 in the symmetrical case.

Valve 200 is useful as a valve at the inlet of a gas system

where a pressurized cylinder is connected as shown in Figure 2. The equalization valve is connected directly to cylinder valve 202 of cylinder 204.

This valve keeps the system positively pressurized when a cylinder is removed while allowing the system to detect when a cylinder is disconnected and reconnected by monitoring the pressure at a pressure sensor (see Figure 1 of the referenced and incorporated disclosure). A normal pressure check valve with the cylinder on the inlet side of the valve would keep the system pressurized when a cylinder is disconnected but would not allow the detection of a cylinder change in all situations. Consider the case where the system is not delivering gas or purging. The pressure on the system side of the check valve would not change when the cylinder was disconnected and then a cylinder of the same or lower pressure was reconnected and the cylinder valve opened. The system could not detect a cylinder change in this scenario.

With the pressure equalization valve, the pressure on the system side of the valve drops to atmospheric pressure plus equalization pressure 2 when a cylinder is removed. The system remains pressurized to greater than atmospheric pressure. When a sufficiently pressurized cylinder is reconnected and the cylinder valve opened, the system pressure rises to the cylinder pressure minus equalization pressure 1. As long as the cylinder pressure

is greater than equalization pressure 1 + equalization pressure 2, the system can detect the cylinder change.

As shown in Figure 3, valve 200 includes a plunger 213 housed inside a valve body 206. Two springs 208 and 210 are located on either side of the plunger. A vented set screw or similar functioning mechanical retainer scheme 212 is located on the system side of the valve and retains the plunger and the springs in the valve. The springs are chosen such that the plunger is positioned so that O-ring 216 is positioned somewhere on sealing surface 218 inside the valve body when the spring forces are equal. It is noted that while the present disclosure refers to an O-ring, any suitable seal or seal element can be used without departing from the scope of the present disclosure. The springs may be chosen to give the desired equalization pressures. If the pressure on the system side of the valve is greater than the pressure on the cylinder side by more than equalization pressure 2, the plunger will be pushed toward the cylinder side until the O-ring clears the sealing surface. This is the situation that will occur if the system side of the valve is pressurized to greater than equalization pressure 2 and the cylinder is removed. Gas will then pass through the valve from the system side to the cylinder side.

Valve channel 220 is larger than valve pin 222 so that gas can flow through the channel. The flow rate through the valve is

limited by the size of orifice 224. If the flow rate is high, the plunger will seat against plunger stop 226 and flow will be throttled. Gas will flow until the pressure on the system side is equal to the pressure on the cylinder side plus equalization pressure 2. At this point, the O-ring will seat on the sealing surface and gas will cease flowing. The plunger will be positioned as shown in Figure 3. The plunger pin 222 fills valve channel 220 so that gas will flow through the channel but large debris does not enter the valve from this side. If gas is not flowing on the system side of the valve, then the system side of the valve will remain pressurized at equalization pressure 2.

When pressure on the cylinder side of the valve is raised to greater than the pressure on the system side plus equalization pressure 1, then the plunger will be pushed toward the system side until the O-ring clears the sealing surface. This will happen when a new pressurized gas source is connected. Gas will then flow through the valve until the pressure on the system side equals the pressure on the cylinder side minus equalization pressure 1. At very high flow rates, the plunger will seat against the set screw or similar functioning mechanical retainer scheme and flow will be throttled. Once the pressure on the system side equals the pressure on the cylinder side minus equalization pressure 1, the O-ring will seat against the sealing surface. The plunger will be positioned as shown in Figure 4.

As can be understood from Figure 3, valve body 206 of the equalizing valve includes a first bore 250 having an inner dimension 252 and a second bore 254 having an inner dimension 256. Inner dimension 256 is larger than inner dimension 252 and a shoulder 258 is defined at the intersection of bore 250 and bore 254. Shoulder 258 is tapered and defines plunger stop 226. Shoulder 258 is located on first end 262 of the second bore which has a second end 264 on which the set screw is mounted. Spring 208 has a first end 266 in abutting contact with the first end of bore 254 and a second end 268 in abutting contact with the plunger. Spring 210 has a first end 270 in abutting contact with the plunger and a second end 272 in abutting contact with the set screw adjacent to the orifice. Plunger 213 has a first end 280 of the first portion of the plunger and a second end 282 of the first end as well as a first end 284 of the second portion of the plunger and a second end 286 of the second portion of the plunger. A longitudinal axis 290 extends between first end 280 and second end 286 of the plunger.

It should be noted that although the bore and plunger cross sections are nominally shown as circular, the functions may be preserved by other cross sectional geometries as long as the associated passages for gas flow and sealing surfaces are maintained. For example, the plunger and bore could be fabricated with a hexagonal or rectangular cross section without changing

the underlying operation of the equalizing valve. In addition, although specific reference in this discussion is made to O-ring seals, this does not preclude the use of other sliding or face seal mechanisms consistent with the general art. For example, properly honed and matched hard surface seals could be incorporated in versions of the equalizing valve where O-rings would be undesirable due to material compatibility problems or where the O-rings could become abraded under severe service.

Several key features of valve 200 are as follows. $|$Cylinder side pressure -system side pressure$|$ $\leq$ equalization pressure when there is no flow. Where the equalization pressure may depend on which side of the valve is at higher pressure.

The system side is kept pressurized when a cylinder is removed as long as gas does not flow from the system side (away from the valve). This helps preserve the cleanliness of the system side circuit.

The pin almost fills the cylinder side of the valve. This has two advantages: this reduces the possibility of debris entering the valve; and reduces the dead space where contaminating gas can be trapped during cylinder changing.

The orifice limits the flow rate through the valve.

Several variations of valve 200 are possible within the scope of the teaching of the present disclosure. As already mentioned, the equalization pressure may or may not be different

when the pressure is greater on the system side than it is when the pressure on the cylinder side is greater. This can be accomplished in several ways. For example, the spring constants of the two springs can be varied. Alternatively, the position and shape of the sealing surface can be altered.

Still further variations of valve 200 are indicated in Figures 5 and 6, with valve 200' in Figure 6 including a plunger 213' which is cylindrical and has a continuous cylindrical wall 230 that is continuous from end 232 to end 234 of the plunger. O-ring 216' fits in a groove defined in cylindrical wall 230. Valve 200" in Figure 6 includes a plunger 213" which is cylindrical and has a wall 230" that includes shoulders 236 and 238 adjacent to end 232" and end 234" respectively of plunger 213". O-ring 216" fits in a groove defined in wall 240 of valve body 206". Wall 240 is continuous and cylindrical.

It can be understood from the foregoing disclosure and from the teaching of the referenced and incorporated disclosure that the equalizing valve of the present invention provides a low dead volume pressure equalizing device that provides a flow versus pressure dead band that provides for zero flow in either direction at non-zero differential pressures. The dead band may be symmetric or asymmetric in differential pressure about zero with respect to a non-zero flow in either direction through the valve. As can be seen in the figures, the pin is sized to

minimize the dead space and the springs have their spring characteristics, including the length as well as the force versus displacement characteristics of the springs so the plunger is located in an intermediate region of plunger travel when flow is prohibited and so the dead band is either symmetric or asymmetric in differential pressure about zero with respect to non-zero flow in each direction. As can also be understood from the foregoing disclosure, the valve can incorporate a progressive flow restriction safety mechanism that prevents high flow rates in the event of an otherwise unconstrained flow.

RESERVOIR

Reservoir 72 is shown in Figures 1 and 7. As shown, reservoir 72 comprises a dip tube 290 which has a fluid inlet end 292 fluidically connected to outlet end 70 of third fluid manifold 92 and an outlet end 294 spaced apart from the inlet end of the dip tube. Hollow housing 78 of the reservoir has an internal volume 298, a first end 300, a second end 302 spaced apart from first end 300 of the hollow housing and a longitudinal axis 304 extending between first end 300 of the hollow housing of the fluid reservoir and second end 302 of the hollow housing of the fluid reservoir. The dip tube is located in the internal volume of the hollow housing of the reservoir and extends in the direction of longitudinal axis 304 of the hollow housing. The outlet end of the dip tube is located adjacent to second end 302

of the hollow housing inside that hollow housing. A fluid outlet 310 is defined in the hollow housing adjacent to first end 300 of the hollow housing and is spaced apart from the second end of the hollow housing. Outlet 310 is fluidically connected to inlet end 74 of the fourth manifold 76 whereby gas flowing from outlet 310 flows into the fourth fluid manifold.

Therapeutic gas flows through the dip tube and out of the end of the dip tube near the second end of the housing. This gas then flows outside of the dip tube in a direction opposite to the gas flowing inside the dip tube and out of outlet 310 and into the fourth fluid manifold. This gas flow is indicated in Figure 7 by arrows GF. The counterflow pattern of the therapeutic gas through the hollow housing helps prevent the gas from stagnating in the remote end of the reservoir. The housing can be equipped with state sensors, such as pressure sensors and can also be equipped with flow sensors that are electrically connected to gauges that inform an operator of conditions existing inside the reservoir. The sensors can also be electrically connected to alarms to alert an operator of undesired conditions in the reservoir. Emptying of the reservoir may be one undesired condition and stagnation may be another such undesired condition while leaks may be yet another undesired condition. Sensors can also be attached to the reservoir to be connected to various alarms and indicators to alert an operator of the operating

status of the reservoir such as full, filling, emptying, purging and the like as well as the remaining amount of gas in the reservoir.

Several other alternative forms of the reservoir are also possible within the scope of the present invention. One alternative form of the reservoir unit does not include a dip tube and another form is shown in Figure 10 as reservoir 72' and has the reservoir inlet also being the reservoir outlet so that fluid flowing into and out of the reservoir flows through the same port. Yet another alternative form of the reservoir is shown in Figure 11 as reservoir 72" and which includes a coiled tube T which tends to prevent the stagnation of gas in the reservoir.

Technical Application

System 10' is shown in Figure 8 and includes appropriate electrical connections as well as alarms and sensors and fluidic connections for two source gases. A selector valve selects one of the two cylinders to provide gas for the patient. An alternative form of the system would include only a single source cylinder without the plumbing for a second cylinder and without a cylinder selector valve. System 10' carries NO/N_2 from the selected source cylinder normally mounted on a cart to the patient circuit as follows. Gas flows from the cylinder at nominally 800 ppm NO (in N_2 balance) through the CGA-626 cylinder fittings on the flexible high pressure hose to a pressure gauge, then through the cylinder

selector valve and plumbing on the cart into the inlet (Main Gas Connection) of the NO delivery device. The cart plumbing includes equalization valves in the CGA-626 cylinder fittings, a purge line with a five psi relief valve connected to the selector valve, a safety burst diaphragm and an ancillary flow regulator for use with a manual resuscitator. The gas in these sections of the system is at roughly supply cylinder pressure except in the purge line, where the pressure is between the cylinder pressure and the five psi relief pressure. The gas can be selected to flow though the ancillary flow regulator on the cart (Manual NO delivery system) to be used with a manual resuscitator while simultaneously maintaining the gas supply to the NO delivery device. In this instance, the cart may also be supplied with flow regulated O_2 to supply the dilution and/or breathing gas for the patient for manual resuscitation.

Once the gas enters the NO delivery device, it passes through the high pressure section. This section contains the CGA-626 inlet nipple, equalization valve and an integrated high-pressure step down regulator delivering 120 psi to the next stage. The main gas connection is supplied with a hand-tightening nut and is followed by a 10 micron gas filter to prevent debris from entering the device. Also included in this section is a 3000 psi electronic pressure sensor to monitor the input pressure and to detect supply pressure changes consistent with changing gas

supply between sources.

Next in the NO/N_2 gas circuit is the medium pressure section that incorporates a five minute reservoir, several solenoid valves, a purge muffler, two safety pressure reliefs and a 25 psi step down regulator. The valves are operated by the main control processor and are used to isolate the gas input to the reservoir, purge the NO delivery device gas circuit or direct gas into the reservoir. The gas stored in the reservoir supplies the system during routine device purges that are performed when a gas source is connected or re-connected, or in the case of both cylinders being allowed to run empty, and will give the operator a few minutes to attach and activate other sources or a back-up system before the system stops the delivery of NO/N_2. This reservoir is a self-flushing design with a dip tube so that gas within it is continuously renewed during normal delivery operation.

The medium pressure section is equipped with two safety reliefs. The first pressure relief, with a 200 psi opening point, is included to protect the reservoir in the event of a failure in the high pressure section. The gas is further pressure reduced by a 25 psi regulator prior to the gas entering the low pressure section. This regulator is followed by a 40 psi pressure relief, intended as protection for downstream components. The embodiment shown in Figure 8 is intended to be illustrative only and it is noted that some of the components shown in Figure 8 can be

located in positions different from those shown in Figure 8 without departing from the scope of this disclosure.

It is noted that while one reservoir housing is shown, a plurality of housings can be used and fluidically interconnected with each other and with the remainder of the system to perform the function of the reservoir. The reservoir can also be separated into sections located in various pressure stages, including a high pressure stage, such as indicated in Figure 1 as stage HP adjacent to the source of gas, a medium pressure stage MP and a low pressure stage LP on the patient side of the system. The reservoir can be operated at pressures significantly higher than ambient pressure, if desired, including operation at the full supply pressure, with a suitable rearrangement of the orientation of a high pressure regulator, the vent solenoid and reservoir solenoid and the reservoir, as shown in Figure 9. If desired, the reservoir can be one large volume that can contain typically as much as five minutes gas supply. However, adding housings may increase this time if desired. In practice, there is no specific limit on the size of the reservoir or reservoirs.

It is noted that the alarms and sensors of system 10 are designed and connected to automatically isolate the reservoir if the supply pressure drops below a preset level and then warn the user that the system is operating on the reservoir. The user will then be alerted to change the source.

PURGING METHOD

The earlier-described system is intended to reduce contamination of the therapeutic gas contained in the pneumatic circuit and to facilitate purging of the pneumatic circuit. The pneumatic circuit must be purged if it becomes contaminated with gas other than the therapeutic gas to help ensure that pure gas is delivered to the patient. For certain therapeutic gases such as NO, even small amounts of air contamination can have serious effects on the gas quality by producing unacceptable levels of NO_2.

There are two types of purge that will be discussed: an overall purge, and a cylinder change purge. The overall purge purges the complete pneumatic circuit downstream of the therapeutic gas source 14. Such a purge will be required at initial commissioning of the system where the pneumatic circuit contained some gas other than the therapeutic gas, and any time the pneumatic circuit integrity is compromised. A cylinder change purge is required when the therapeutic gas source 14 is reconnected to the system, such as at a cylinder change event. The therapeutic gas source is typically a high-pressure gas cylinder. This discussion of purging will refer to a supply cylinder, although other types of therapeutic gas source may be used. A small amount of air is trapped between the cylinder valve V1 and the first equalization valve 12 when the cylinder is

reconnected to the system and air may also be trapped inside the cylinder valve V1.

Purging is accomplished by replacing contaminated gas in the pneumatic circuit with clean therapeutic gas derived from the supply cylinder 14. There are two principle methods of purging: flow rinsing and dilution. Flow rinsing works by simply flowing gas through the pneumatic circuit. Clean gas from the supply cylinder 14 enters the pneumatic circuit and flows through the swept regions of the circuit, pushing most of the contaminated gas out in front of it. There may be still be some contamination remaining that is adsorbed on the pneumatic circuit surfaces. The swept regions are parts of the pneumatic circuit where gas can flow continuously in a single direction. These regions have a separate entrance and exit and the entire region is swept out as gas flows through. Dilution purging works by pressurizing a region by adding clean gas, allowing it to mix with the contaminated gas, and then depressurizing the region, removing some of the contaminated gas. This method can purge unswept regions where flow through is not possible. It also purges swept regions and may accomplish flow rinsing of these regions as well.

The underlying method by which the system can be effectively purged in the case of either an overall purge or a cylinder change purge is based upon repeated pressurization and depressurization of the volume being purged. This action combines

flow rinsing of the actively swept regions and surfaces with dilution purging of the unswept regions as they are repeatedly pressurized and depressurized with progressively less contaminated gas. In the system that is being described, this basic operation is performed many times in a controlled sequence by repeatedly pressurizing and depressurizing the gas within the affected volumes while periodically venting portions of the gas, to enhance the rinsing and dilution effects.

It should be understood that where the terms measure, monitor, open, close and the like are used, that in the context of manual, semi-automated or fully automatic systems, these functions could be optionally or alternatively controlled either through the manual intervention of the operator or through the use of computerized control, without the underlying method being affected.

The overall purge process consists of two major sequences. These sequences are called, the "Front End Purge" and the "Reservoir Purge".

Efficient use of the purge gas during the "Front End Purge" occurs using the following sequence controlling the flow and shunting of purge gas. It should be noted that many portions of the gas plumbing affected by these purge steps operate at relatively high pressures, so that even comparatively small physical volumes may hold disproportionate amounts of gas within

the context of the overall plumbing circuit.

Step 1: Close all the automated solenoid valves in the system. Charge the front end of the system plumbing with fresh gas from the supply cylinder 14 by opening the cylinder valve. The front end consists of the first equalization valve 12, the first fluid conduit 16, the second equalization valve 20, the first fluid manifold 90, the high pressure regulator 40 and the second fluid manifold 91 including up to the upstream sides of the solenoid purge valve 54 and the reservoir solenoid valve 64. The cylinder valve V1 is also purged by this process.

Step 2: Allow a short period (typically a few seconds) for the gas pressures to rise past a minimum threshold as monitored by the pressure sensor 36 for the flow in the front end to stop. This pause also allows time for the clean gas to mix with the contaminated gas, which will enhance dilution purging.

Step 3: Vent a small amount of gas (typically 20 to 50 ml at STP) out of the system through solenoid purge valve (54). This step is provided to assist venting gas that was present in the plumbing at the time of the initial charging that would be compressed into the small volume adjacent the solenoid purge valve.

Step 4: Open the reservoir solenoid valve 64 and allow the reservoir 72 and the remaining downstream gas system through to the fifth fluid manifold 95 to fill to their working pressure

levels.

Step 5: Close the supply valve on the cylinder 14.

Step 6: Close the reservoir solenoid valve 64 and open the solenoid purge valve 54. Allow the gas in the front end to vent until the pressure as measured by pressure sensor 36 is higher than, but approaching, atmospheric pressure. During this step, the pressures in the volumes on either sides of the equalization valves will also collapse, but only so far as the equalization pressure differential allows.

Step 7: Close the solenoid purge valve 54 and open the reservoir solenoid valve 64 to allow the front end and reservoir pressures to equalize. In this case, the gas flow is backward to the normal flow, that is the gas pressure in the reservoir forces gas from the reservoir back into the comparatively low pressure region formed by the front end. In this case, as long as the pressure in the reservoir is high enough to force gas back through the front end plumbing, including the equalization valve isolated sections, the front end will be rinsed by the same gas that already went through once in the other direction.

Step 8: Repeat steps 6 and 7 until there is insufficient gas to continue as measured by the reservoir pressure sensor 80. Typically this requires 6 to 8 cycles through steps 6 and 7.

Step 9: Repeat steps 1 through 8 a number of times (typically 5 repetitions in the case of NO as the supply gas).

This completes the “Front End Purge”.

At this point in the overall purge process, the initial sections of the gas plumbing have already been pressurized and depressurized numerous times. However, because this pressurization and depressurization was conducted using gas that was shifted back and forth in the system, the overall amount of gas consumed (or otherwise released into the immediate environment) was comparatively much less than if fresh gas were to be drawn for each pressurization event.

The second portion of the purge process, the “Reservoir Purge” is conducted according to the following sequence.

Step 10: Open the supply 14 cylinder value and perform steps 1, 2, 3 and 4.

Step 11: Close the reservoir solenoid valve 64 and begin to dispense gas out of the reservoir and out through the downstream gas path as during normal operation. Monitor the pressure in the reservoir using the reservoir pressure sensor (80) and continue dispensing gas until the reservoir pressure drops to above but near atmospheric pressure.

Step 12: Refill the reservoir by opening the reservoir solenoid valve 64 and allow the reservoir 72 and the remaining downstream gas system through to the fifth fluid manifold 95 to fill to their working pressure levels.

Step 13: Repeat steps 11 and 12 a number of times (typically

five repetitions) to rinse and dilute to safe levels any remaining contaminants in the reservoir and other gas path components.

The reservoir purge portion of the overall purge conserves gas compared to a simple flow through technique since it combines the flow through with pressurization and depressurization (dilution). As a result, less net gas is required to reduce contamination to equivalent levels.

The combination of the "Front End Purge" and the "Reservoir Purge"steps provides for an effective purge of the entire gas system, using a minimal amount of supply gas.

The cylinder change purge occurs when the system detects that a cylinder has been reconnected to the system. This event is detected when the pressure at pressure sensor 36 drops when a cylinder is disconnected and later rises when a cylinder is reconnected and the cylinder valve is opened. The ability to sense both the rising and falling pressures while still isolating the majority of the circuit from the environment is provided by the equalizing valves' action. The system may be delivering gas when a cylinder change occurs. The system will be running on reservoir (any delivered gas comes from the reservoir) from the time that a cylinder is disconnected until a cylinder change purge is completed. The reservoir can supply gas to the patient for a limited amount of time in this condition and the cylinder

change and purge take some time to complete. Because of this, it is desirable to be able to top up the reservoir prior to the completion of the cylinder change purge if this can be accomplished without contaminating the gas in the reservoir. The cylinder change purge consists of the following steps, which occur after a cylinder is reconnected to the system:

Step 14: Open the cylinder 14 valve.

Step 15: The system detects the reconnection of a cylinder when the pressure at the pressure sensor 36 rises above a threshold pressure.

Step 16: Vent a small amount of gas (typically 500 to 1000 ml at STP) out of the system through solenoid purge valve 54. This step is provided to vent gas that was present in the plumbing at the time of the initial charging that would be compressed into the small volume adjacent the solenoid purge valve.

Step 17: Open the reservoir solenoid valve 64 and close the solenoid purge valve 54 a short time later (typically 100 ms). Allow the reservoir pressure to come up to its regular working pressure. The gas that enters the reservoir at this point will be clean because gas in the swept regions of the pneumatic circuit upstream of the reservoir solenoid valve was cleaned during step 16. There may still be contaminated gas in the unswept regions upstream of the reservoir solenoid valve at this

point though.

Step 18: Close the reservoir solenoid valve 64.

Step 19: Close the cylinder 14 valve.

Step 20: Open the solenoid purge valve 54. Allow the gas in the front end to vent until the pressure as measured by pressure sensor 36 is higher than but approaching atmospheric pressure. During this step, the pressures in the volumes on either sides of the equalization valves will also collapse, but only so far as the equalization pressure differential allows.

Step 21: Repeat steps 14, 16-20 several times (typically 4 times).

Step 22: Open the cylinder 14 valve.

Step 23: Open the reservoir solenoid valve 64 and leave open.

It is understood that while certain forms of the present invention have been illustrated and described herein, it is not to be limited to the specific forms or arrangements of parts described and shown.